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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,536	02/10/2004	James J. Rudnick	S63.2N-14438-US05	6703

490 7590 02/01/2011
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EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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02/01/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/775,536	Applicant(s) RUDNICK ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-36 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/2/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3774

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-36 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant's disclosure and drawings do not describe or clearly show the stent's windings being in direct contact with each other when the stent is in its unexpanded configuration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead (US Pat. No. 5,019,085) in view of Kanazawa (JP 07024072). Hillstead discloses the following of the claimed invention: an elongate tubular stent (12) formed of a helically wound wire defining a plurality of wire waves wherein said wire waves are longitudinally nested within each other; the stent having an unexpanded state (col. 2, lines 27-44), the plurality of wire waves

Art Unit: 3774

comprising a first wire wave and a second wire wave (Figs. 3-4), the first wire wave being longitudinally adjacent to the second wire wave; the stent having a length (Figs. 3-4); and a lumen (Figs. 3-4). The waves have varying amplitudes with the waves adjacent the ends of the stent having a smaller amplitude than those waves in-between (please see Figures 3-4). The stent may be constructed into various patterns from a single, continuous helically wound wire (Fig. 3). Regarding the limitations describing the waves being in direct contact with one another and the peak to peak distance between the waves, the Hillstead reference does not explicitly state that the windings of the stent will contact each other or have the claimed peak-to-peak distance. However, Hillstead discloses the stent being made of a flexible stainless steel wire which is capable of being compressed into various configurations which may include the windings being in contact with each other and the claimed peak-to-peak distance (col. 2, lines 27-44; col. 3, lines 24-30).

Hillstead does not teach applying a cover with a solid structure having pores and elasticity to the stent. Kanazawa teaches a stent with a solid, porous cover of tetra-fluoroethylene resin as taught in the abstract for the purpose of providing the stent with improved biocompatibility and antithrombogenesis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to place a cover on the stent of Hillstead in order to provide the stent with improved biocompatibility and antithrombogenesis.

Please note that the examiner is interpreting the terms “film” and “membrane” by their dictionary definitions. “Film” is defined as “a thin sheet of any material” (film. Dictionary.com. Dictionary.com Unabridged (v 1.1). Random House, Inc. <http://dictionary.reference.com/browse/film> (accessed: May 07, 2008)). “Membrane” is defined

Art Unit: 3774

as “a thin pliable sheet of material” (membrane. Dictionary.com. WordNet® 3.0. Princeton University. <http://dictionary.reference.com/browse/membrane> (accessed: May 07, 2008)). The stent covering described in the Kanazawa reference meets the limitations of these terms, as set forth by their respective definitions.

Response to Arguments

Applicant's arguments filed 7/6/2010 have been fully considered but they are not persuasive. The Applicant contends that the term “nested” must be given its broadest, reasonable interpretation in light of the specification. However, unless the specification has explicitly defined the term "nested" to mean that the peak-to-peak amplitude of longitudinally adjacent windings that is less than 2A, these limitations may not be read into the claims. Therefore, the previous interpretation of the term “nested” has been maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit
3774

/A. S./
Examiner, Art Unit 3774